a distal tip section at said distal end portion of said shaft,

said distal tip section comprising fluorinated ethylene propylene containing between about 20% and 75% by weight of radiopaque material selected from the group consisting of tungsten, titanium, tantalum, platinum, gold, silver, bismuth trioxide and lead, and

said shaft being distinctly less radiopaque than said distal section.

New claims 15 and 16 are added to the case:

15. (new) The introducer sheath of claim 14, wherein said shaft comprises fluorinated ethylene propylene.

16. (new) The introducer sheath of claim 1, wherein said shaft comprises fluorinated ethylene propylene.

REMARKS

This Amendment and Response is responsive to the first Office Action mailed April 24, 2002. Presently, all claims 1-14 stand rejected. Applicants respectfully request re-examination and reconsideration of the claim rejections in view of the claim amendments and the remarks provided herein.

In this Amendment and Response, the applicants have amended claim 1, cancelled claims 3 and 7-9 and added new claims 15 and 16 to the case. A marked-up version of amended claim 1 is provided below:

1. (Amended) An introducer sheath comprising:

a shaft extending from a proximal end portion to a distal end portion; and

a distal tip section at said distal end portion of said shaft,

said distal tip section comprising [a polymeric material] fluorinated ethylene

propylene containing [over] between about 20% and [up to about] 75% by weight of radiopaque material selected from the group consisting of tungsten, titanium, tantalum, platinum, gold, silver, bismuth trioxide and lead, and

said shaft being distinctly less radiopaque than said distal section.

Section 102 rejections

Claims 1-4, 7 and 13 were rejected under 35 USC §102(e) as being clearly anticipated by each of Trotta and Castillo '880. Claims 1-4, 7 and 13 were also rejected under 35 USC §102(b) as being anticipated by Parker '270.

The Trotta patent discloses a soft tip torsion control catheter. According to the disclosure, the soft tip torsion control catheter employs a specified copolymer composition that is easily modifiable to a particular use by altering the relative amounts of the various monomers in the copolymer. In addition, the copolymer is said to bond better to stiffer body materials, such as nylon 11 and nylon 12, than prior art polyamide block copolymers. The soft tip portion is formed from a copolymer including a first monomer of polyamide and a second monomer having a polyamide backbone with a seven carbon side chain. Col. 3., lines 8-11. The soft tip may also include nylon 11 or nylon 12 blended with the copolymer. Col. 4, lines 11-12. Preferably, the soft tip comprises polyurethane, such as a polyether-polyurethane or polyester-polyurethane blend. Col. 11, lines 64-67. The distal tip material includes a radiopaque compound in an amount of from about 10% to about 60% by weight. The preferred composition of the catheter body is a polyamide.

The Castillo '880 patent discloses a catheter sheath introducer having a polyolefin distal tip containing up to 90 wt % of a radiopaque metal powder. Preferably the polyolefin is low density polyethylene. According to the disclosure, the method used in making the polyolefin compound results in the radiopaque metal powder being substantially uniformly distributed and held within a polymer matrix. The polyolefin is heated to its melting temperature and a high amount (up to 90 wt %) of a radiopaque metal is added. A dispersing (wetting) agent made from a stearate must then be added, thereby forming a stable radiopaque polymer compound wherein the metal powder is uniformly dispersed throughout

and well bonded in the compound. Col. 2, lines 37-47. The body of the introducer is preferably made from the same base polyolefin as the tip.

The Parker '270 patent discloses a soft tip guiding catheter having a main tubular portion and a soft tubular tip. The soft tip preferably comprised as a soft durometer polyether block amide material such as nylon. The soft tip can be loaded with tungsten to increase the radiopacity of the soft tip.

None of the three cited §102 references discloses a soft tip made from fluorinated ethylene propylene (FEP), as claimed in independent claims 1 (as amended) and 14. According to the patent specification, it is unexpected that high loadings of tungsten, titanium, tantalum, platinum, gold, silver, bismuth trioxide and lead could be attained with FEP, and yet still result in a stable extrudable composition that can be bonded at least to other FEP material. See, application, page 4, lines 21-29. A loading of 20% tungsten results in a radiopacity that is roughly equivalent to that generated by a 40% loading of barium sulphate. See, application, page 4, lines 21-29. FEP sheaths have heretofore contained about 5 to 40% barium sulphate filler. FEP is not known to be fillable to over 40% with barium sulphate particles and still result in a stable extrudable composition. It is believed that the irregular, nonspherical shape of the metal particles, along with the high density of the metal, small particle size and narrow size distribution range may permit such high loading levels in the present invention. Page 4, lines 26-34.

Section 103 rejections

Claims 5, 6 and 14 were rejected under 35 USC §103(a) as being unpatentable over Parker '270 in view of Hopkins. According to the Examiner, Parker discloses all of the recited structure with the exception of the size of the tungsten particles used. The patent to Hopkins discloses the use of tungsten radiopaque particles as small as 0.9 microns in a marker band 14. The marker band, made of a heat shrinkable material, is heat shrunk over a catheter or sheath. The tube of marker band material comprises between 10 and 80 percent by weight metal particles and between 90 and 20 percent by weight plastic material. However, these percentages relate to the amount of metal in the marker band, and not in the

actual distal tip as in the present invention. As stated in the Background of the present application, it is known to use annular radiopaque marker bands that are secured within the outer surface of the sheath adjacent the distal tip. One of the advantages of the present invention is that the radiopaque marking can be viewed exactly at the distal tip, rather than spaced from the tip as when a marker band is used, in order to best assure exact positioning by the surgeon. One of ordinary skill in the art would not look to the Hopkins reference, because it teaches away from the present teachings of a radiopaque distal tip, rather than having a marker band on the tip.

As stated previously, the Parker reference discloses a soft tip guiding catheter having a main tubular portion and a soft tubular tip comprised of a soft durometer polyether block amide material such as nylon. It does not teach the use of FEP. The addition of the Hopkins reference does not overcome this shortcoming.

Claims 8-10 were rejected under 35 USC §103(a) as being unpatentable over Parker '270 in view of Garabedian. According to the Examiner, the Garabedian reference discloses that it is known in the art to use fluorinated ethylene propylene as sleeves in catheters. The Garabedian reference discloses an intravascular catheter having an inner lubricious layer, a braided reinforcement layer, and an outer layer, none of which are disclosed as being formed from FEP. A radiopaque marker band 60 formed of gold, tungsten or the like is disposed over the reinforcement layer adjacent the distal end of the catheter shaft. A heat shrink tube formed of a polymeric composition such as FEP is placed over the components of the elongate catheter shaft 12, and the subassembly is pulled through a heated die. After the die is heated, the heat shrink tube is removed, exposing the completed shaft subassembly. Col. 7, lines 2-8.

As in the prior art, Garabedian utilizes a marker band that is placed adjacent the distal end of the shaft. This marker band includes the radiopaque metallic particles and is spaced form the distal end of the shaft, similar to that in Hopkins. The FEP appears to be used solely as a heat shrink tube, which is thereafter removed from the subassembly after the remaining components are fused and compressed together. Nowhere does Garabedian teach or even suggest to form the sheath or a distal tip of FEP, or that FEP sheaths can be loaded

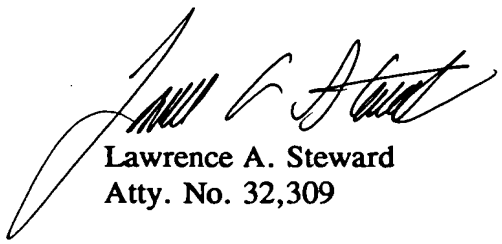
with a radiopaque material such as the radiopaque materials in the claims. Since the sole use of FEP is as a heat shrink tube which is removed from the finished product, the skilled artisan would be led in a direction away from the present invention, wherein FEP is used in a soft distal tip.

Claims 11 and 12 were rejected under 35 USC §103(a) as being unpatentable over Parker '270 in view of Garabedian as applied to claims 8-10, and further in view of Hopkins. All of these references have been discussed previously. Claims 11 and 12 specify the size of the tungsten particles. Notwithstanding the teaching of tungsten particles as small as 0.9 microns in Hopkins, nothing in the cited combination teaches or suggests the desirability of utilizing FEP as a sheath material, and loading that FEP with radiopaque materials as claimed herein.

New claims 15 and 16 have been added to the case. Claims 15 and 16 specify that the shaft material comprises FEP. These claims are supported in the specification at p. 4, lines 21-23.

Based upon the foregoing, Applicants respectfully submit that claims 1, 2, 4-6 and 10-16 are in condition for allowance. Accordingly, Applicants respectfully request the issuance of a Notice of Allowance. If the Examiner believes that the prosecution of this application may be expedited by a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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